UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/524,507	09/29/2005	Ivo Paul Touw	3691-050510	6240

28289 7590 10/04/2007

THE WEBB LAW FIRM, P.C.
700 KOPPERS BUILDING
436 SEVENTH AVENUE
PITTSBURGH, PA 15219

EXAMINER	
POPA, ILEANA	
ART UNIT	**PAPER NUMBER**
1633	

MAIL DATE	DELIVERY MODE
10/04/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/524,507	TOUW ET AL.	
	Examiner	Art Unit	
	Ileana Popa	1633	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 52-75 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 52-75 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Claims 1-51 have been cancelled. Claims 52-75 are new.

Claims 52-75 are pending.

Election/Restrictions

2. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions, which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 52 and 54-56, drawn to an isolated nucleic acid.

Group II, claim(s) 53 and 72, drawn to a method of preparing an inhibitor.

Group III, claim(s) 52 and 57-64, drawn to a method of treating cancer by using an inhibitor compound.

Group IV, claim(s) 65, drawn to a method of treating cancer by using a hematopoietic stem cell.

Group V, claim(s) 66-71, drawn to a method of diagnosing cancer.

Group VI, claim(s) 73-75, drawn to a method of identifying genomic regions involved in the development of cancer.

3. The inventions listed as Groups I-VI do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

A) The invention has no special technical feature that defined the contribution

over the prior art, **or**

B) Unity of invention between different categories of inventions will only be found to exist if specific combinations of inventions are present. Those combinations include:

1) A product and a special process of manufacture of said product.

2) A product and a process of use of said product.

3) A product, a special process of manufacture of said product, and a process of use of said product.

4) A process and an apparatus specially designed to carry out said process.

5) A product, a special process of manufacture of said product, and an apparatus specially designed to carry out said process.

The allowed combinations do not include multiple products, multiple methods of using said products, and methods of making multiple products, see MPEP § 1850. It is noted that the instant claims are drawn to multiple methods of using the product.

Applicant's claims encompass multiple inventions and do not have a special technical feature which link the inventions one to the other, and lack unity of invention. The invention of Group I is drawn to a nucleic acid, while the inventions of Groups II-VI are drawn to methods of preparing an inhibitor, of treating cancer, or of cancer diagnostic. Thus, it follows from the preceding analysis that the claimed inventions listed as Groups I-VI do not relate to a single inventive concept under PCT rule 13.1, because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the reasons set forth above.

Species Election

4. Should invention of Group I be elected for prosecution, a further species election is required as follows between patentably distinct species

Claim 52 is generic to a plurality of disclosed patentably distinct species comprising:

- Distinct species of genomic regions.

Applicant is required to elect a single disclosed species of genomic region, even though this requirement is traversed.

The above species are distinct because they are drawn to distinct genomic regions that require different searches in the patent and non-patent literature.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

5. Should invention of Group II be elected for prosecution, a further species election is required as follows between patentably distinct species:

Claim 53 is generic to a plurality of disclosed patentably distinct species comprising:

- Distinct species of inhibitors.

Applicant is required to elect a single disclosed species of inhibitor, even though this requirement is traversed.

The above species are distinct because they are drawn to distinct compositions that require different searches in the patent and non-patent literature.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

6. Should invention of Group III be elected for prosecution, a further species election is required as follows between patentably distinct species:

Claim 52 is generic to a plurality of disclosed patentably distinct species comprising:

- Distinct species of genomic regions.

Applicant is required to elect a single disclosed species of genomic region, even though this requirement is traversed.

The above species are distinct because they are drawn to distinct genomic regions that require different searches in the patent and non-patent literature.

Claims 57 and 58 are generic to a plurality of disclosed patentably distinct species of inhibitors comprising:

- antibodies, antisense, RNAi, ribozyme, or small molecule.

Applicant is required to elect a single disclosed species of inhibitor, even though this requirement is traversed.

Should antibody be elected for prosecution, a further species election is required between scFv fragments, Fab fragments, chimeric antibodies, bifunctional antibodies, intrabodies, or other antibody-derived molecules.

Should the species of "other antibody-derived molecules" be elected for prosecution, Applicant is required to precisely disclose the identity of the antibody-derived molecules

The above species are distinct because they are drawn to distinct compositions that require different searches in the patent and non-patent literature.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

In addition to the above:

This application contains claims directed to the following patentably distinct species:

- cancer (claims 59, 60, 63, and 64) and inflammatory diseases (claim 62)

The species are independent or distinct because they are drawn to distinct diseases that require different searches in the patent and non-patent literature.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 52, 57, 58, and 61 are generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

7. Should invention of Group VI be elected for prosecution, a further species election is required as follows between patentably distinct species

Claim 75 is generic to a plurality of disclosed patentably distinct species comprising:

- Distinct species of genomic regions.

Applicant is required to elect a single pair of disclosed species of genomic

regions, even though this requirement is traversed.

The above species are distinct because they are drawn to distinct genomic regions that require different searches in the patent and non-patent literature.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

8. Inventions of Groups II and VI are patentably distinct because each is drawn to a distinct method, such as a method of preparing an inhibitor, of treating cancer, of diagnosing cancer, or of identifying genomic region involved in the development of cancer; each method requires different steps and compositions for practice and results in a different outcome. For these reasons, the methods necessitate different searches in the patent and non-patent literature and different considerations under 112, first paragraph, and/or 102/103(a). Therefore, a search and examination of anything more than one of the above inventions would be a burden fro the Examiner.

Inventions of Group I and III-V are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different

designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, the nucleic acid of Group I cannot be used to treat cancer or to diagnose cancer.

Inventions of Groups I and II are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case the nucleic acid of Group I can be used to identify genomic region involved in the development of cancer.

Inventions of Groups I and VI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case the nucleic acid of Group I can be used to prepare inhibitors.

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is

found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of In re Ochiai, In re Brouwer and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

9. Because these inventions are distinct for the reasons given above and the search required for each of the Groups above is not required for the others, restriction for examination purposes as indicated is proper. Similarly, the species election is proper because they are drawn to distinct compositions that have different structure and mode of action. Since they represent distinct subject matter, it would be unduly burdensome for the Examiner to search all the inventions and species being sought in the pending claims.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ileana Popa whose telephone number is 571-272-5546. The examiner can normally be reached on 9:00 am-5:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Woitach can be reached on 571-272-0739. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Ileana Popa, PhD

/Joseph Woitach/

Joseph Woitach

SPE 1633